



DEPARTMENT OF HEALTH & HUMAN SERVICES

NFD-613

Food and Drug Administration  
Rockville MD 20857

DEC 9 1998

NDA 18-537/S-015

Faulding Pharmaceutical Co.  
A subsidiary of Faulding Inc.  
Attention: Ms. Iris Feliciano  
11 Commerce Drive  
Cranford, NJ 07016

Dear Ms. Feliciano:

Please refer to your supplemental new drug application dated October 27, 1998 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tridil (nitroglycerin) Injection.

This supplemental new drug application provides for final printed labeling revised by the addition of the following paragraph in bold print as the first warning under **WARNINGS**:

Amplification of the vasodilatory effects of Tridil by sildenafil can result in severe hypotension. The time course and dose dependence of this interaction have not been studied. Appropriate supportive care has not been studied, but it seems reasonable to treat this as a nitrate overdose, with elevation of the extremities and with central volume expansion.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your October 27, 1998 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In addition, at your next printing, please change "children" to "pediatric patients" in the **Pediatric Use** statement. A supplemental application need not be submitted to implement this change. It should, however, be reported in your annual report.

If you have any questions, please contact:

Mr. Gary Buehler  
Regulatory Health Project Manager  
(301) 594-5332

Sincerely yours,

Raymond J. Lipicky, M.D.  
Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research